

Amendments to the Claims

Please amend the claims according to the following listing.

Current Listing of Claims

1. (currently amended) A method for evaluating the glycosylated hemoglobin (HbA<sub>1c</sub>) of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:  
  
preparing the data for estimating HbA<sub>1c</sub> using a predetermined sequence of mathematical formulas defined as:  
  
pre-processing of the data[[;]],  
  
estimating HbA<sub>1c</sub> by applying [[using]] at least one of four predetermined formulas to said data[[;]], and  
  
validation of the estimate via sample selection criteria; and  
  
outputting the estimate to a user.
2. (original) The method of claim 1, wherein said first predetermined duration is about 60 days.
3. (original) The method of claim 1, wherein said first predetermined duration ranges from about 45 days to about 75 days.
4. (original) The method of claim 1, wherein said first predetermined duration ranges from about 45 days to about 90 days.
5. (currently amended) The method of claim 1, wherein the preprocessing of the data for each patient comprise:

conversion of plasma data to whole blood BG mg/dl;  
conversion of BG measured in mg/dl to units of mmol/l;  
and  
computing Low Blood Glucose Index (RLO1) and High  
Blood Glucose Index (RHI1).

6. (currently amended) The method of claim 1, wherein the preprocessing of the data for each patient using predetermined mathematical formulas is defined as:

conversion of plasma to whole blood BG mg/dl via  
 $BG = PLASBG \text{ (mg/dl)} / 1.12$ ;  
conversion of BG measured in mg/dl to units of mmol/l)  
via  $BGMM = BG / 18$ ; and  
computing Low Blood Glucose Index (RLO1) and High  
Blood Glucose Index (RHI1) using a predetermined  
mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$ , wherein BG is  
measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$ , wherein

$RiskLO = Risk1$  if (BG is less than about 112.5) and  
therefore risk of LBGI exists, otherwise  
 $RiskLO = 0$ , and

$RiskHI = Risk1$  if (BG is greater than about 112.5)  
and therefore risk of HBGI exists, otherwise  
 $RiskHI = 0$ ,

$BGMM1 = \text{average of } BGMM \text{ per patient,}$

$RLO1 = \text{average of } RiskLO \text{ per patient,}$

$RHI1 = \text{average of } RiskHI \text{ per patient,}$

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals ,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

7. (original) The method of claim 6, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
8. (original) The method of claim 6, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is  $\leq$  about 5.25 or if RHI1 is  $\geq$  about 16)  
then the assigned group= 0,  
  
if (RHI1 is  $>$  about 5.25 and if RHI1 is  $<$  about 7.0 ) then the assigned group=1,  
  
if (RHI1 is  $\geq$  about 7.0 and if RHI1 is  $<$  about 8.5 ) then the assign group=2, and  
  
if (RHI1 is  $\geq$  about 8.5 and if RHI1 is  $<$  about 16)  
then the assigned group=3.

9. (original) The method of claim 8, comprising providing estimates using a predetermined mathematical formula defined as:

$E0 = 0.55555 * BGMM1 + 2.95,$   
 $E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$   
 $E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$   
 $E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65;$  and  
 if (Group = 1) then EST2=E1, or if (Group = 2)  
 then EST2=E2, or if (Group = 3) then EST2=E3,  
 otherwise EST2=E0.

10. (original) The method of claim 9, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,  
 if (RLO1 is  $\leq$  about 0.5 and RHI1 is  $\leq$  about 2.0)  
 then EST2=E0-0.25,  
 if (RLO1 is  $\leq$  about 2.5 and RHI1 is  $>$  about 26 )  
 then EST2=E0-1.5\*RLO1, and  
 if ((RLO1/RHI1) is  $\leq$  about 0.25 and L06 is  $>$  about  
 1.3) then EST2=EST2-0.08.

11. (previously presented) The method of claim 10 for estimating the HbA<sub>1c</sub> of a patient based on BG data collected over the first predetermined duration, said method comprising:

said estimating HbA<sub>1c</sub> using said at least one of four predetermined mathematical formulas defined as:

- a) HbA<sub>1c</sub> = the EST2 defined by claim 8 or as corrected by claim 10 or  
 b)  $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 + 1.873325,$  wherein

BGMM1 is the average BG (mmol/l) of claim 6.

RLO1 is the Low BG Index of claim 6.

RHI1 is the High BG Index of claim 6; or

- c)  $HbA1c = 0.682742 \cdot HBA0 + 0.054377 \cdot RHI1 + 1.553277$ ,  
wherein

HBA0 is a previous reference HbA1c reading taken  
about a second predetermined period prior to the  
estimate, wherein

RHI1 = is the High BG Index of claim 6; or

- d)  $HbA1c = 0.41046 \cdot BGMM + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 6.

12. (original) The method of claim 11, wherein said second predetermined duration is about three months.
13. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
14. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to six months.
15. (original) The method of claim 11, wherein the validation of the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:
  - a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

- b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;
  - c) a randomness of data criterion-1 wherein the HbA<sub>1c</sub> estimate is validated or displayed only if the ratio  $(RLO1/RHI1 \geq \text{about } 0.005)$ ,  
wherein  
RLO1 is the Low BG Index of claim 6  
RHI1 is the High BG Index of claim 6; or
  - d) a randomness of data criterion-2 wherein HbA<sub>1c</sub> estimate is validated or displayed only if the ratio  $(N06 \geq \text{about } 3\%)$ .  
wherein  
N06 is the percentage of readings during the night of claim 6.
16. (original) The method of claim 15, wherein said third predetermined duration is at least 35 days.
17. (original) The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about 40 days.
18. (original) The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.
19. (currently amended) A system for evaluating the HbA<sub>1c</sub> of a patient based on BG data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

prepare the data for estimating  $HbA_{1c}$  using a predetermined sequence of mathematical formulas defined as:

pre-process the data,

estimate  $HbA_{1c}$  by applying [[using]] at least one of four predetermined formulas to said data, and

validate the estimate via sample selection criteria; and

output the estimate to a user.

20. (original) The system of claim 19, wherein said first predetermined duration is about 60 days.

21. (original) The system of claim 19, wherein said first predetermined duration ranges from about 45 days to about 75 days.

22. (original) The system of claim 19, wherein said first predetermined duration ranges from about 45 days to about 90 days.

23. (original) The system of claim 19, wherein the preprocessing of the data for each patient comprise:  
conversion of plasma to whole blood BG mg/dl;  
conversion of BG measured in mg/dl to units of mmol/l;  
and  
computing Low Blood Glucose Index (RL01) and High Blood Glucose Index (RHI1).

24. (currently amended) The system of claim 19, wherein the preprocessing of the data for each patient using predetermined mathematical formulas is defined as:
- conversion of plasma to whole blood BG mg/dl via  $BG = PLASBG \text{ (mg/dl)} / 1.12$ ;
- conversion of BG measured in mg/dl to units of mmol/l) via  $BGMM = BG / 18$ ; and
- computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:
- $Scale = [\ln(BG)]^{1.0845} - 5.381$ , wherein BG is measured in units of mg/dl,
- $Risk1 = 22.765(Scale)^2$ , wherein
- $RiskLO = Risk1$  if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise  $RiskLO = 0$ , and
- $RiskHI = Risk1$  if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise  $RiskHI = 0$ ,
- $BGMM1$  = average of BGMM per patient,
- $RLO1$  = average of RiskLO per patient,
- $RHI1$  = average of RiskHI per patient,
- $L06$  = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,
- $N06$ ,  $N12$ ,  $N24$  are percentage of SMBG readings in time intervals ,
- $NC1$  = total number of SMBG readings in the first



predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

25. (original) The system of claim 24, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
26. (original) The system of claim 24, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:
- if (RHI1 is  $\leq$ about 5.25 or if RHI1 is  $\geq$ about 16)  
then the assigned group= 0,
- if (RHI1 is  $>$  about 5.25 and if RHI1 is  $<$  about 7.0 ) then the assigned group=1,
- if (RHI1 is  $\geq$ about 7.0 and if RHI1 is  $<$  about 8.5 ) then the assign group=2, and
- if (RHI1 is  $\geq$ about 8.5 and if RHI1 is  $<$ about 16)  
then the assigned group=3.
27. (original) The system of claim 26, comprising providing estimates using a predetermined mathematical formula defined as:
- $E0 = 0.55555 \cdot BGMM1 + 2.95,$
- $E1 = 0.50567 \cdot BGMM1 + 0.074 \cdot L06 + 2.69,$
- $E2 = 0.55555 \cdot BGMM1 - 0.074 \cdot L06 + 2.96,$
- $E3 = 0.44000 \cdot BGMM1 + 0.035 \cdot L06 + 3.65;$  and
- if (Group = 1) then EST2=E1, or if (Group = 2)

then  $EST2=E2$ , or if (Group = 3) then  $EST2=E3$ ,  
otherwise  $EST2=E0$ .

28. (original) The system of claim 27, comprising  
providing further correction of the estimates using a  
predetermined mathematical formula defined as:

if (missing(L06))  $EST2=E0$ ,  
if (RLO1 is  $\leq$  about 0.5 and RHI1 is  $\leq$  about 2.0)  
then  $EST2=E0-0.25$ ,  
if (RLO1 is  $\leq$  about 2.5 and RHI1 is  $>$  about 26 )  
then  $EST2=E0-1.5*RLO1$ , and  
if ((RLO1/RHI1) is  $\leq$  about 0.25 and L06 is  $>$  about  
1.3) then  $EST2=EST2-0.08$ .

29. (previously presented) The system of claim 28 for  
estimating the  $HbA_{1c}$  of a patient based on BG data  
collected over the first predetermined duration, said  
system comprising:

said estimating  $HbA_{1c}$  using said at least one of four  
predetermined mathematical formulas defined as:

- a)  $HbA_{1c}$  = the  $EST2$  defined by claim 8 or as  
corrected by claim 10 or  
b)  $HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 -$   
 $0.151673*RHI1 + 1.873325$ , wherein  
 $BGMM1$  is the average BG (mmol/l) of claim 24,  
 $RLO1$  is the Low BG Index of claim 24,  
 $RHI1$  is the High BG Index of claim 24; or  
c)  $HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277$ ,  
wherein

HBA0 is a previous reference HbA1c reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 24; or

d) 
$$\text{HbA1c} = 0.41046 \cdot \text{BGMM} + 4.0775$$

wherein BGMM1 is the average BG (mmol/l) of claim 24.

30. (original) The system of claim 29, wherein said second predetermined duration is about three months.
31. (original) The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
32. (original) The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to six months.
33. (previously presented) The system of claim 29, wherein the validation of the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:
  - a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
  - b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

- c) a randomness of data criterion-1 wherein the HbA<sub>1c</sub> estimate is validated or displayed only if the ratio  $(RLO1/RHI1 \geq \text{about } 0.005)$ , wherein  
RLO1 is the Low BG Index of claim 24,  
RHI1 is the High BG Index of claim 24; or
  - d) a randomness of data criterion-2 wherein HbA<sub>1c</sub> estimate is validated or displayed only if the ratio  $(N06 \geq \text{about } 3\%)$ , wherein  
N06 is the percentage of readings during the night of claim 24.
34. (original) The system of claim 33, wherein said third predetermined duration is at least 35 days.
35. (original) The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about 40 days.
36. (original) The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.
37. (currently amended) A system for evaluating the HbA<sub>1c</sub> of a patient based on BG data collected over a first predetermined duration, said system comprising:
- a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;
  - a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

prepare the data for estimating  $HbA_{1c}$  using a predetermined sequence of mathematical formulas defined as:

pre-process the data;

estimate  $HbA_{1c}$  by applying [[using]] at least one of four predetermined formulas to said data; and

validate the estimate via sample selection criteria.

38. (currently amended) A computer program product comprising a computer useable medium having computer program logic for enabling at least one processor in a computer system to evaluate the  $HbA_{1c}$  of a patient based on BG data collected over a first predetermined duration, said computer program logic comprising:

preparing the data for estimating  $HbA_{1c}$  using a predetermined sequence of mathematical formulas defined as:

pre-processing of the data,

estimating  $HbA_{1c}$  by applying [[using]] at least one of four predetermined formulas to said data, and

validation of the estimate via sample selection criteria; and

outputting the estimate to a user.

39. (original) The computer program product of claim 38, wherein said computer program logic further comprises

the steps of claim 11.

40. (withdrawn) A method for evaluating the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a predetermined duration, said method comprising:
- computing LBGI based on said collected BG data;
  - and
  - estimating the number of future SH episodes using a predetermined mathematical formula based on said computed LBGI.

41. (withdrawn) The method of claim 40, wherein:
- said computed LBGI is mathematically defined from a series of BG readings  $x_1, x_2, \dots, x_n$  taken at time points  $t_1, t_2, \dots, t_n$  as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

where:

$lbgi(BG; a) = 10 \cdot f(BG)^a$  if  $f(BG) > 0$  and 0 otherwise,

a = about 2, representing a weighting parameter.

42. (withdrawn) The method of claim 40, further comprising:
- defining predetermined risk categories(RCAT), each of said risk categories(RCAT) representing a range of values for LBGI; and
  - assigning said LBGI to at least one of said risk

categories(RCAT).

43. (withdrawn) The method of claim 42, wherein said risk categories(RCAT) are defined as follows:

category 1, wherein said LBGI is less than about 0.25;

category 2, wherein said LBGI is between about 0.25 and about 0.50;

category 3, wherein said LBGI is between about 0.50 and about 0.75;

category 4, wherein said LBGI is between about 0.75 and about 1.0;

category 5, wherein said LBGI is between about 1.0 and about 1.25;

category 6, wherein said LBGI is between about 1.25 and about 1.50;

category 7, wherein said LBGI is between about 1.5 and about 1.75;

category 8, wherein said LBGI is between about 1.75 and about 2.0;

category 9, wherein said LBGI is between about 2.0 and about 2.5;

category 10, wherein said LBGI is between about 2.5 and about 3.0

category 11, wherein said LBGI is between about 3.0 and about 3.5;

category 12, wherein said LBGI is between about 3.5 and about 4.25;

category 13, wherein said LBGI is between about 4.25

and about 5.0;

category 14, wherein said LBGI is between about 5.0 and about 6.5; and

category 15, wherein said LBGI is above about 6.5.

44. (withdrawn) The method of claim 42, further comprising:

defining a probability of incurring a select number of SH episodes respectively for each of said assigned risk categories(RCAT).

45. (withdrawn) The method of claim 42, further comprising:

defining a probability of incurring a select number of SH episodes within a next first predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$  for any  $x > 0$  and 0 otherwise,  
wherein:

a = about -4.19,

b = about 1.75.

46. (withdrawn) The method of claim 45, wherein said first predetermined duration is about one month.

47. (withdrawn) The method of claim 45, wherein said first predetermined duration ranges from about 0.5 months to about 1.5 months.

48. (withdrawn) The method of claim 45, wherein said first predetermined duration ranges from about 0.5 months to about 3 months.

49. (withdrawn) The method of claim 42, further



comprising:

defining a probability of incurring a select number of SH episodes within a next second predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a.x^b)$  for any  $x > 0$  and 0 otherwise,  
wherein:

a = about -3.28,

b = about 1.50.

50. (withdrawn) The method of claim 49, wherein said second predetermined duration is about three months.

51. (withdrawn) The method of claim 49, wherein said second predetermined duration ranges from about 2 months to about 4 months.

52. (withdrawn) The method of claim 49, wherein said second predetermined duration ranges from about 3 months to about 6 months.

53. (withdrawn) The method of claim 42, further comprising:

defining a probability of incurring a select number of SH episodes within the next third predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a.x^b)$  for any  $x > 0$  and 0 otherwise,  
wherein:

a = about -3.06,

b = about 1.45.

54. (withdrawn) The method of claim 53, wherein said third

predetermined duration is about 6 months.

55. (withdrawn) The method of claim 53, wherein said third predetermined duration ranges from about 5 months to about 7 months.

56. (withdrawn) The method of claim 53, wherein said third predetermined duration ranges from about 3 months to about 9 months.

57. (withdrawn) The method of claim 42, further comprising:

defining a probability of incurring a select number of MH episodes within the next month respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$  for any  $x > 0$  and 0 otherwise,  
wherein:

a = about -1.58,

b = about 1.05.

58. (withdrawn) The method of claim 42, further comprising:

defining a probability of incurring a select number of MH episodes within the next 3 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$  for any  $x > 0$  and 0 otherwise,  
wherein:

a = about -1.37,

b = about 1.14.

59. (withdrawn) The method of claim 42, further

comprising:

defining a probability of incurring a select number of MH episodes within the next 6 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$  for any  $x > 0$  and 0 otherwise,

wherein:

a = about -1.37,

b = about 1.35.

60. (withdrawn) The method of claim 40, further comprising:

assigning classifications of risk for future significant hypoglycemia of the patient.

61. (withdrawn) The method of claim 60, wherein said classifications are defined as follows:

minimal risk, wherein said LBGI is less than about 1.25;

low risk, wherein said LBGI is between about 1.25 and about 2.50;

moderate risk, wherein said LBGI is between about 2.5 and about 5; and

high risk, wherein said LBGI is above about 5.0.

62. (withdrawn) A system for evaluating the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a predetermined duration, said system comprising:

a database component operative to maintain a database

identifying said BG data; and

a processor programmed to:

compute LBGI based on said collected BG data, and  
estimate the number of future SH episodes using a  
predetermined mathematical formula based on said  
computed LBGI.

63. (withdrawn) The method of claim 62, wherein:

said computed LBGI is mathematically defined from a  
series of BG readings  $x_1, x_2, \dots, x_n$  taken at time  
points  $t_1, t_2, \dots, t_n$  as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

where:

$lbgi(BG; a) = 10 \cdot f(BG)^a$  if  $f(BG) > 0$  and 0  
otherwise,

$a = \text{about } 2$ , representing a weighting  
parameter.

64. (withdrawn) The system of claim 62, further  
comprising:

defining predetermined risk categories(RCAT), each of  
said risk categories(RCAT) representing a range of  
values for LBGI; and

assigning said LBGI to at least one of said risk  
categories(RCAT).

65. (withdrawn) The system of claim 64, wherein said risk  
categories (RCAT) are defined as follows:

category 1, wherein said LBGI is less than about 0.25;

category 2, wherein said LBGI is between about 0.25 and about 0.50;

category 3, wherein said LBGI is between about 0.50 and about 0.75;

category 4, wherein said LBGI is between about 0.75 and about 1.0;

category 5, wherein said LBGI is between about 1.0 and about 1.25;

category 6, wherein said LBGI is between about 1.25 and about 1.50;

category 7, wherein said LBGI is between about 1.5 and about 1.75;

category 8, wherein said LBGI is between about 1.75 and about 2.0;

category 9, wherein said LBGI is between about 2.0 and about 2.5;

category 10, wherein said LBGI is between about 2.5 and about 3.0

category 11, wherein said LBGI is between about 3.0 and about 3.5;

category 12, wherein said LBGI is between about 3.5 and about 4.25;

category 13, wherein said LBGI is between about 4.25 and about 5.0;

category 14, wherein said LBGI is between about 5.0 and about 6.5; and

category 15, wherein said LBGI is above about 6.5.

66. (withdrawn) The system of claim 64, further comprising:  
  
defining a probability of incurring a select number of SH episodes respectively for each of said assigned risk categories (RCAT).
67. (withdrawn) The system of claim 64, further comprising:  
  
defining a probability of incurring a select number of SH episodes within a next first predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:  
  
$$F(x) = 1 - \exp(-a.x^b) \text{ for any } x > 0 \text{ and } 0 \text{ otherwise,}$$
  
wherein:  
  
a = about -4.19,  
  
b = about 1.75.
68. (withdrawn) The system of claim 67, wherein said first predetermined duration is about one month.
69. (withdrawn) The system of claim 67, wherein said first predetermined duration ranges from about 0.5 months to about 1.5 months.
70. (withdrawn) The system of claim 67, wherein said first predetermined duration ranges from about 0.5 months to about 3 months.
71. (withdrawn) The system of claim 64, further comprising:  
  
defining a probability of incurring a select number of SH episodes within a next second predetermined duration respectively for each of said assigned risk

categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a.x^b)$  for any  $x > 0$  and  $0$  otherwise,  
wherein:

$a$  = about  $-3.28$ ,

$b$  = about  $1.50$ .

72. (withdrawn) The system of claim 71, wherein said second predetermined duration is about three months.
73. (withdrawn) The system of claim 71, wherein said second predetermined duration ranges from about 2 months to about 4 months.
74. (withdrawn) The system of claim 71, wherein said second predetermined duration ranges from about 3 months to about 6 months.
75. (withdrawn) The system of claim 64, further comprising:  
  
defining a probability of incurring a select number of SH episodes within the next third predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:  
  
 $F(x) = 1 - \exp(-a.x^b)$  for any  $x > 0$  and  $0$  otherwise,  
wherein:  
  
 $a$  = about  $-3.06$ ,  
  
 $b$  = about  $1.45$ .
76. (withdrawn) The system of claim 75, wherein said third predetermined duration is about 6 months.
77. (withdrawn) The system of claim 75, wherein said third predetermined duration ranges from about 5 months to about 7 months.

78. (withdrawn) The system of claim 75, wherein said third predetermined duration ranges from about 3 months to about 9 months.

79. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of MH episodes within the next month respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$  for any  $x > 0$  and 0 otherwise, wherein:

a = about -1.58,

b = about 1.05.

80. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of MH episodes within the next 3 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - \exp(-a \cdot x^b)$  for any  $x > 0$  and 0 otherwise, wherein:

a = about -1.37,

b = about 1.14.

81. (withdrawn) The system of claim 64, further comprising:

defining a probability of incurring a select number of MH episodes within the next 6 months respectively for each of said assigned risk categories(RCAT), using the



formula:

$F(x) = 1 - \exp(-a \cdot x^b)$  for any  $x > 0$  and 0 otherwise,  
wherein:

a = about -1.37,

b = about 1.35.

82. (withdrawn) The system of claim 62, further comprising:

assigning classifications of risk for future significant hypoglycemia of the patient.

83. (withdrawn) The system of claim 82, wherein said classifications are defined as follows:

minimal risk, wherein said LBGI is less than about 1.25;

low risk, wherein said LBGI is between about 1.25 and about 2.50;

moderate risk, wherein said LBGI is between about 2.5 and about 5; and

high risk, wherein said LBGI is above about 5.0.

84. (withdrawn) A system for evaluating the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

compute LBGI based on said collected BG data, and  
estimate the number of future SH episodes using a  
predetermined mathematical formula based on said  
computed LBGI.

85. (withdrawn) A computer program product comprising a  
computer useable medium having computer program logic  
for enabling at least one processor in a computer  
system to evaluate the long term probability for  
severe hypoglycemia (SH) and/or moderate hypoglycemia  
(MH) of a patient based on BG data collected over a  
predetermined duration, said computer program logic  
comprising:

computing LBGI based on said collected BG data; and  
estimating the number of future SH episodes using a  
predetermined mathematical formula based on said  
computed LBGI.

86. (withdrawn) The computer program product of claim 85,  
wherein said computer program logic further comprises  
the steps of claim 42.

87. (withdrawn) A method for evaluating the short term  
probability for severe hypoglycemia (SH) of a patient  
based on BG data collected over a predetermined  
duration, said method comprising:

computing scale values based on said collected BG  
data; and

computing the low BG risk value (RLO) for each BG  
data.

88. (withdrawn) The method of claim 87, wherein:

said computed  $RLO(BG)$  is mathematically defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$ , wherein  $BG$  is measured in units of mg/dl

$Risk = 22.765(Scale)^2$

if ( $BG$  is less than about 112.5) then:

$RLO(BG) = Risk$ , otherwise

$RLO(BG) = 0$ .

89. (withdrawn) The method of claim 87, wherein:

said computed  $RLO(BG)$  is mathematically defined as:

$Scale = [\ln(BG)]^{1.026} - 1.861$ , wherein  $BG$  is measured in units of mmol/l

$Risk = 32.184(Scale)^2$

if ( $BG$  is  $\leq$  about 112.5) then:

$RLO(BG) = Risk$ , otherwise

$RLO(BG) = 0$ .

90. (withdrawn) The method of claim 87, wherein:

computing  $LBGI$  based on said collected  $BG$  data, said computed  $LBGI$  is mathematically defined from a series of  $BG$  readings  $x_1, x_2, \dots, x_n$  taken at time points  $t_1, t_2, \dots, t_n$  as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

where:

$$lbgi(BG; a) = RLO(BG).$$

91. (withdrawn) The method of claim 87, wherein:

computing provisional  $LBGI$  based on said collected  $BG$

data, said computed provisional LBGI is mathematically defined from mathematically defined as:

$$\text{LBGI}(1) = \text{RLO}(x_1)$$

$$\text{RLO2}(1) = 0$$

$$\text{LBGI}(j) = ((j-1)/j) * \text{LBGI}(j-1) + (1/j) * \text{RLO}(x_j)$$

$$\text{RLO2}(j) = ((j-1)/j) * \text{RLO2}(j-1) + (1/j) * (\text{RLO}(x_j) - \text{LBGI}(j))^2.$$

92. (withdrawn) The method of claim 91, wherein:

computing SBGI, said computed SBGI is mathematically defined as:

$$\text{SBGI}(n) = \sqrt{\text{RLO2}(n)}.$$

93. (withdrawn) The method of claim 92, comprising qualifying or providing a warning of upcoming short term SH wherein if:

$(\text{LBGI}(150) \geq 2.5 \text{ and } \text{LBGI}(50) \geq (1.5 * \text{LBGI}(150) \text{ and } \text{SBGI}(50) \geq \text{SBGI}(150))$  then said issue of warning is qualified or provided, or

$\text{RLO} \geq (\text{LBGI}(150) + 1.5 * \text{SBGI}(150))$  then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided.

94. (withdrawn) The method of claim 92, comprising qualifying or providing a warning of upcoming short term SH wherein if:

$(\text{LBGI}(n) \geq \alpha \text{ and } \text{SBGI}(n) \geq \beta)$  then said issue of warning is qualified or provided, and/or

$(\text{RLO}(n) \geq (\text{LBGI}(n) + \gamma * \text{SBGI}(n)))$  then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided, wherein  $\alpha$ ,  $\beta$ , and  $\gamma$  are threshold parameters.

95. (withdrawn) The method of claim 94, wherein said threshold parameters  $\alpha$ ,  $\beta$ , and  $\gamma$  are defined as  $\alpha$  = about 5,  $\beta$  = about 7.5,  $\gamma$  = about 1.5.

96. (withdrawn) The method of claim 94, wherein said threshold parameters  $\alpha$ ,  $\beta$ , and  $\gamma$  are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a)  $\alpha$  = 6.4,  $\beta$  = 8.2,  $\gamma$  = 1.5,  $\alpha$  = 5.0,  $\beta$  = 7.5,  $\gamma$  = 1.3;

b)  $\alpha$  = 6.0,  $\beta$  = 7.5,  $\gamma$  = 1.5,  $\alpha$  = 4.9,  $\beta$  = 7.0,  $\gamma$  = 1.2; and/or

c)  $\alpha$  = 5.5,  $\beta$  = 7.5,  $\gamma$  = 1.5,  $\alpha$  = 4.8,  $\beta$  = 7.0,  $\gamma$  = 1.2.

97. (withdrawn) The method of claim 94, wherein said threshold parameters  $\alpha$ ,  $\beta$ , and  $\gamma$  are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a).  $\alpha$  about 6.4,  $\beta$  about 8.2,  $\gamma$  about 1.5,  $\alpha$  about 5.0,  $\beta$  about 7.5,  $\gamma$  about 1.3;

b).  $\alpha$  about 6.0,  $\beta$  about 7.5,  $\gamma$  about 1.5,  $\alpha$  about 4.9,  $\beta$  about 7.0,  $\gamma$  about 1.2; and/or

c).  $\alpha$  about 5.5,  $\beta$  about 7.5,  $\gamma$  about 1.5,  $\alpha$  about 48,

$\beta$  about 7.0,  $\gamma$  about 1.2.

98. (withdrawn) A system for evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

compute scale values based on said collected BG data;  
and

compute the low BG risk value (RLO) for each BG data.

99. (withdrawn) The system of claim 98, wherein:

said computed RLO(BG) is mathematically defined as:

Scale =  $[\ln(\text{BG})]^{1.0845} - 5.381$ , wherein BG is measured in units of mg/dl

Risk =  $22.765(\text{Scale})^2$

if (BG is less than about 112.5) then:

RLO(BG) = Risk, otherwise

RLO(BG) = 0.

100. (withdrawn) The system of claim 98, wherein:

said computed RLO(BG) is mathematically defined as:

Scale =  $[\ln(\text{BG})]^{1.026} - 1.861$ , wherein BG is measured in units of mmol/l

Risk =  $32.184(\text{Scale})^2$

if (BG is  $\leq$  about 112.5) then:

RLO(BG) = Risk, otherwise

$$\text{RLO}(\text{BG}) = 0.$$

101. (withdrawn) The system of claim 98, wherein:

computing LBGI based on said collected BG data, said computed LBGI is mathematically defined from a series of BG readings  $x_1, x_2, \dots, x_n$  taken at time points  $t_1, t_2, \dots, t_n$  as:

$$\text{LBGI} = \frac{1}{n} \sum_{i=1}^n \text{lbgi}(x_i; 2)$$

where:

$$\text{lbgi}(\text{BG}; a) = \text{RLO}(\text{BG}).$$

102. (withdrawn) The system of claim 98, wherein:

computing provisional LBGI based on said collected BG data, said computed provisional LBGI is mathematically defined from mathematically defined as:

$$\text{LBGI}(1) = \text{RLO}(x_1)$$

$$\text{RLO2}(1) = 0$$

$$\text{LBGI}(j) = ((j-1)/j) * \text{LBGI}(j-1) + (1/j) * \text{RLO}(x_j)$$

$$\text{RLO2}(j) = ((j-1)/j) * \text{RLO2}(j-1) + (1/j) * (\text{RLO}(x_j) - \text{LBGI}(j))^2.$$

103. (withdrawn) The system of claim 102, wherein:

computing SBGI, said computed SBGI is mathematically defined as:

$$\text{SBGI}(n) = \sqrt{\text{RLO2}(n)}.$$

104. (withdrawn) The system of claim 103, comprising qualifying or providing a warning of upcoming short term SH wherein if:

$(LBGI(150) \geq 2.5 \text{ and } LBGI(50) \geq (1.5 * LBGI(150) \text{ and } SBGI(50) \geq SBGI(150))$  then said issue of warning is qualified or provided, or

$RLO \geq (LBGI(150) + 1.5 * SBGI(150))$  then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided.

105. (withdrawn) The system of claim 103, comprising qualifying or providing a warning of upcoming short term SH wherein if:

$(LBGI(n) \geq \alpha \text{ and } SBGI(n) \geq \beta)$  then said issue of warning is qualified or provided, and/or

$(RLO(n) \geq (LBGI(n) + \gamma * SBGI(n)))$  then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided, wherein  $\alpha$ ,  $\beta$ , and  $\gamma$  are threshold parameters.

106. (withdrawn) The system of claim 105, wherein said threshold parameters  $\alpha$ ,  $\beta$ , and  $\gamma$  are defined as  $\alpha =$  about 5,  $\beta =$  about 7.5,  $\gamma =$  about 1.5.

107. (withdrawn) The system of claim 105, wherein said threshold parameters  $\alpha$ ,  $\beta$ , and  $\gamma$  are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a)  $\alpha = 6.4$ ,  $\beta = 8.2$ ,  $\gamma = 1.5$ ,  $\alpha = 5.0$ ,  $\beta = 7.5$ ,  $\gamma = 1.3$ ;



b)  $\alpha = 6.0$ ,  $\beta = 7.5$ ,  $\gamma = 1.5$ ,  $\alpha = 4.9$ ,  $\beta = 7.0$ ,  $\gamma = 1.2$ ; and/or

c)  $\alpha = 5.5$ ,  $\beta = 7.5$ ,  $\gamma = 1.5$ ,  $\alpha = 4.8$ ,  $\beta = 7.0$ ,  $\gamma = 1.2$ .

108. (withdrawn) The system of claim 105, wherein said threshold parameters  $\alpha$ ,  $\beta$ , and  $\gamma$  are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a).  $\alpha$  about 6.4,  $\beta$  about 8.2,  $\gamma$  about 1.5,  $\alpha$  about 5.0,  $\beta$  about 7.5,  $\gamma$  about 1.3;

b).  $\alpha$  about 6.0,  $\beta$  about 7.5,  $\gamma$  about 1.5,  $\alpha$  about 4.9,  $\beta$  about 7.0,  $\gamma$  about 1.2; and/or

c).  $\alpha$  about 5.5,  $\beta$  about 7.5,  $\gamma$  about 1.5,  $\alpha$  about 4.8,  $\beta$  about 7.0,  $\gamma$  about 1.2.

109. (withdrawn) A system for evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

compute scale values based on said collected BG data;  
and

compute the low BG risk value (RLO) for each BG data.

110. (withdrawn) A computer program product comprising a computer useable medium having computer program logic for enabling at least one processor in a computer system to evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said computer program logic comprising:

computing scale values based on said collected BG data; and

computing the low BG risk value (RLO) for each BG data.

111. (withdrawn) The computer program product of claim 110, wherein said computer program logic further comprises the steps of claim 92.

112. (original) The method of claim 11, wherein the validation of the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio  $(RLO1/RHI1 \geq \text{about } 0.005)$ ,

wherein

RLO1 is the Low BG Index of claim 6

RHI1 is the High BG Index of claim 6; or

- c) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio (NO6  $\geq$  about 3%),

wherein

N06 is the percentage of readings during the night of claim 6.

113. (original) The method of claim 112, wherein said third predetermined duration is at least about 35 days.

114. (previously presented) The system of claim 29, wherein the validation of the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

- b) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio (RLO1/RHI1  $\geq$  about 0.005),

wherein

RLO1 is the Low BG Index of claim 24

RHI1 is the High BG Index of claim 24; or

- c) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio (NO6  $\geq$  about 3%),

wherein

N06 is the percentage of readings during the night of claim 24.

115. (original) The system of claim 114, wherein said third predetermined duration is at least about 35 days.
116. (previously presented) The system of claim 37, wherein said first predetermined duration is about 60 days.
117. (previously presented) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 75 days.
118. (previously presented) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 90 days.
119. (currently amended) The system of claim 37, wherein the preprocessing of the data for each patient comprise:
- conversion of plasma data to whole blood BG mg/dl;
  - conversion of BG measured in mg/dl to units of mmol/l;
  - and
  - computing Low Blood Glucose Index (RL01) and High Blood Glucose Index (RHI1).
120. (currently amended) The system of claim 37, wherein the preprocessing of the data for each patient using predetermined mathematical formulas is defined as:
- conversion of plasma data to whole blood BG mg/dl via  $BG = PLASBG \text{ (mg/dl)} / 1.12$ ;
  - conversion of BG measured in mg/dl to units of mmol/l) via  $BGMM = BG / 18$ ; and
  - computing Low Blood Glucose Index (RL01) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$ , wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$ , wherein

$RiskLO = Risk1$  if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise  $RiskLO = 0$ , and

$RiskHI = Risk1$  if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise  $RiskHI = 0$ ,

BGMM1 = average of BGMM per patient,

RL01 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

121. (previously presented) The system of claim 120, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

122. (previously presented) The system of claim 120, comprising assigning a group depending on the

patient's computed High BG Index using a predetermined mathematical formula defined as:

```
if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16)
then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about
7.0 ) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5
) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16)
then the assigned group=3.
```

123. (previously presented) The system of claim 122, comprising providing estimates using a predetermined mathematical formula defined as:

```
E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2)
then EST2=E2, or if (Group = 3) then EST2=E3,
otherwise EST2=E0.
```

124. (previously presented) The system of claim 123, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

```
if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is ≤ about 2.0)
then EST2=E0-0.25,
```

if (RLO1 is  $\leq$  about 2.5 and RHI1 is  $>$  about 26 )  
then  $EST2 = E0 - 1.5 * RLO1$ , and  
if ((RLO1/RHI1) is  $\leq$  about 0.25 and L06 is  $>$  about  
1.3) then  $EST2 = EST2 - 0.08$ .

125. (previously presented) The system of claim 124 for  
estimating the  $HbA_{1c}$  of a patient based on BG data  
collected over the first predetermined duration, said  
system comprising:

said estimating  $HbA_{1c}$  using said at least one of four  
predetermined mathematical formulas defined as:

- a)  $HbA_{1c}$  = the  $EST2$  defined by claim 8 or as  
corrected by claim 10 or
- b)  $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 -$   
 $0.151673 * RHI1 + 1.873325$ , wherein  
 $BGMM1$  is the average BG (mmol/l) of claim 120,  
 $RLO1$  is the Low BG Index of claim 120,  
 $RHI1$  is the High BG Index of claim 120; or
- c)  $HbA_{1c} = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$ ,  
wherein  
 $HBA0$  is a previous reference  $HbA_{1c}$  reading taken  
about a second predetermined period prior to the  
estimate, wherein  
 $RHI1$  = is the High BG Index of claim 120; or
- d)  $HbA_{1c} = 0.41046 * BGMM + 4.0775$

wherein  $BGMM1$  is the average BG (mmol/l) of claim 120.

126. (previously presented) The system of claim 125,  
wherein said second predetermined duration is about

three months.

127. (previously presented) The system of claim 125, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

128. (previously presented) The system of claim 125, wherein said second predetermined duration ranges from about 2.5 months to six months.

129. (previously presented) The system of claim 125, wherein the validation of the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
- b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;
- c) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio  $(RLO1/RHI1 \geq \text{about } 0.005)$ , wherein  
  
RLO1 is the Low BG Index of claim 120,  
  
RHI1 is the High BG Index of claim 120; or
- d) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio  $(NO6 \geq \text{about } 3\%)$ ,



wherein

N06 is the percentage of readings during the night of claim 120.

130. (previously presented) The system of claim 129, wherein said third predetermined duration is at least 35 days.
131. (previously presented) The system of claim 129, wherein said third predetermined duration ranges from about 35 days to about 40 days.
132. (previously presented) The system of claim 129, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.
133. (previously presented) The system of claim 125, wherein the validation of the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:
- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
  - b) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio  $(RLO1/RHI1 \geq \text{about } 0.005)$ ,
- wherein
- RLO1 is the Low BG Index of claim 120
- RHI1 is the High BG Index of claim 120; or

c) a randomness of data criterion-2 wherein HbA<sub>1c</sub> estimate is validated or displayed only if the ratio (N06  $\geq$  about 3%),

wherein

N06 is the percentage of readings during the night of claim 120.

134. (previously presented) The system of claim 133, wherein said third predetermined duration is at least about 35 days.

135. (currently amended) A method for evaluating the HbA<sub>1c</sub> of a patient based on BG data collected over a first predetermined duration, said method comprising:

preparing the data for estimating HbA<sub>1c</sub> using a predetermined sequence of mathematical formulas defined as:

pre-processing of the data<sub>[[;]]</sub>,<sub>␣</sub>

validation of a sample of the BG data via sample selection criteria<sub>[[;]]</sub>,<sub>␣</sub> and

estimating HbA<sub>1c</sub> from said BG data if the sample is valid; and

outputting the estimate to a user.

136. (previously presented) The method of claim 135, wherein said first predetermined duration is about 60 days.

137. (previously presented) The method of claim 135, wherein said first predetermined duration ranges from about 45 days to about 75 days.

138. (previously presented) The method of claim 135,

wherein said first predetermined duration ranges from about 45 days to about 90 days.

139. (previously presented) The method of claim 135, wherein the preprocessing of the data for each patient comprise:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l;

and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

140. (currently amended) The method of claim 135, wherein the preprocessing of the data for each patient using predetermined mathematical formulas is defined as:

conversion of plasma to whole blood BG mg/dl via

$BG = PLASBG \text{ (mg/dl)} / 1.12$ ;

conversion of BG measured in mg/dl to units of mmol/l)

via  $BGMM = BG / 18$ ; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$ , wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$ , wherein

$RiskLO = Risk1$  if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise  $RiskLO = 0$ , and

$RiskHI = Risk1$  if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise

RiskHI=0,  
BGMM1 = average of BGMM per patient,  
RLO1 = average of RiskLO per patient,  
RHI1 = average of RiskHI per patient,  
L06 = average of RiskLO computed only for  
readings during the night, otherwise missing if  
there are no readings at night,  
N06, N12, N24 are percentage of SMBG readings in  
time intervals ,  
NC1 = total number of SMBG readings in the first  
predetermined duration; and  
NDAYS = number of days with SMBG readings in the  
first predetermined duration.

141. (previously presented) The method of claim 140,  
wherein the N06, N12, N24 are percentage of SMBG  
readings in time intervals of about 0-6:59 hour time  
period; about 7-12:59 hour time period, and about 18-  
23:59 hour time period, respectively.
142. (previously presented) The method of claim 140,  
comprising assigning a group depending on the  
patient's computed High BG Index using a predetermined  
mathematical formula defined as:
- if (RHI1 is  $\leq$ about 5.25 or if RHI1 is  $\geq$ about 16) then  
the assigned group= 0,  
if (RHI1 is  $>$  about 5.25 and if RHI1 is  $<$  about 7.0 )  
then the assigned group=1,  
if (RHI1 is  $\geq$ about 7.0 and if RHI1 is  $<$  about 8.5 )  
then the assign group=2, and

if (RHI1 is  $\geq$  about 8.5 and if RHI1 is  $<$  about 16) then  
the assigned group=3.

143. (previously presented) The method of claim 142,  
comprising providing estimates using a predetermined  
mathematical formula defined as:

$$E0 = 0.55555 * BGMM1 + 2.95,$$

$$E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$$

$$E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$$

$$E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65; \text{ and}$$

if (Group = 1) then  $EST2 = E1$ , or if (Group = 2) then  
 $EST2 = E2$ , or if (Group = 3) then  $EST2 = E3$ , otherwise  
 $EST2 = E0$ .

144. (previously presented) The method of claim 143,  
comprising providing further correction of the  
estimates using a predetermined mathematical formula  
defined as:

if (missing(L06))  $EST2 = E0$ ,

if (RLO1 is  $\leq$  about 0.5 and RHI1 is  $\leq$  about 2.0) then  
 $EST2 = E0 - 0.25$ ,

if (RLO1 is  $\leq$  about 2.5 and RHI1 is  $>$  about 26 ) then  
 $EST2 = E0 - 1.5 * RLO1$ , and

if ((RLO1/RHI1) is  $\leq$  about 0.25 and L06 is  $>$  about 1.3)  
then  $EST2 = EST2 - 0.08$ .

145. (previously presented) The method of claim 144 for  
estimating the  $HbA_{1c}$  of a patient based on BG data  
collected over the first predetermined duration, said  
method comprising:

estimating  $HbA_{1c}$  using at least one of four

predetermined mathematical formulas defined as:

- a)  $HbA_{1c}$  = the EST2 defined by claim 8 or as corrected by claim 10 or
- b)  $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 + 1.873325$ , wherein  
BGMM1 is the average BG (mmol/l) of claim 140.  
RLO1 is the Low BG Index of claim 140.  
RHI1 is the High BG Index of claim 140; or
- c)  $HbA_{1c} = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$ , wherein  
HBA0 is a previous reference HbA1c reading taken about a second predetermined period prior to the estimate, wherein  
RHI1 = is the High BG Index of claim 140; or
- d)  $HbA_{1c} = 0.41046 * BGMM + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 140.

146. (previously presented) The method of claim 145, wherein said second predetermined duration is about three months.
147. (previously presented) The method of claim 145, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
148. (previously presented) The method of claim 145, wherein said second predetermined duration ranges from about 2.5 months to six months.
149. (previously presented) The method of claim 145, wherein the validation of the sample using sample

selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
- b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;
- c) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio  $(RL01/RHI1 \geq \text{about } 0.005)$ ,  
wherein  
RL01 is the Low BG Index of claim 140  
RHI1 is the High BG Index of claim 140; or
- d) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio  $(N06 \geq \text{about } 3\%)$ .  
wherein  
N06 is the percentage of readings during the night of claim 140.

150. (previously presented) The method of claim 149, wherein said third predetermined duration is at least 35 days.

151. (previously presented) The method of claim 149, wherein said third predetermined duration ranges from

about 35 days to about 40 days.

152. (previously presented) The method of claim 149, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.
153. (previously presented) The method of claim 145, wherein the validation of the sample using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:
- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
  - b) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio  $(RLO1/RHI1 \geq \text{about } 0.005)$ , wherein  
  
RLO1 is the Low BG Index of claim 149  
  
RHI1 is the High BG Index of claim 140; or
  - c) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio  $(NO6 \geq \text{about } 3\%)$ , wherein  
  
NO6 is the percentage of readings during the night of claim 140.
154. (previously presented) The method of claim 153, wherein said third predetermined duration is at least about 35 days.



155. (currently amended) A system for evaluating the HbA<sub>1c</sub> of a patient based on BG data collected over a first predetermined duration, said system comprising:
- a database component operative to maintain a database identifying said BG data; and
  - a processor programmed to:
    - prepare the data for estimating HbA<sub>1c</sub> using a predetermined sequence of mathematical formulas defined as:
      - pre-process the data,
      - validate a sample of the BG data via sample selection criteria, and
      - estimate HbA<sub>1c</sub> from said BG data if the sample is valid; and
      - output the estimate to a user.
156. (previously presented) The system of claim 155, wherein said first predetermined duration is about 60 days.
157. (previously presented) The system of claim 155, wherein said first predetermined duration ranges from about 45 days to about 75 days.
158. (previously presented) The system of claim 155, wherein said first predetermined duration ranges from about 45 days to about 90 days.
159. (previously presented) The system of claim 155, wherein the preprocessing of the data for each patient comprise:
- conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l;  
and

computing Low Blood Glucose Index (RLO1) and High  
Blood Glucose Index (RHI1).

160. (currently amended) The system of claim 155, wherein  
the preprocessing of the data for each patient using  
predetermined mathematical formulas is defined as:

conversion of plasma to whole blood BG mg/dl via  
 $BG = PLASBG \text{ (mg/dl)} / 1.12$ ;

conversion of BG measured in mg/dl to units of mmol/l)  
via  $BGMM = BG / 18$ ; and

computing Low Blood Glucose Index (RLO1) and High  
Blood Glucose Index (RHI1) using a predetermined  
mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$ , wherein BG is measured in  
units of mg/dl,

$Risk1 = 22.765(Scale)^2$ , wherein

$RiskLO = Risk1$  if (BG is less than about 112.5) and  
therefore risk of LBGI exists, otherwise  $RiskLO = 0$ , and

$RiskHI = Risk1$  if (BG is greater than about 112.5) and  
therefore risk of HBGI exists, otherwise  $RiskHI = 0$ ,

$BGMM1 =$  average of BGMM per patient,

$RLO1 =$  average of RiskLO per patient,

$RHI1 =$  average of RiskHI per patient,

$L06 =$  average of RiskLO computed only for readings  
during the night, otherwise missing if there are no  
readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals ,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

161. (previously presented) The system of claim 160, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
162. (previously presented) The system of claim 160, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:
- if (RHI1 is  $\leq$  about 5.25 or if RHI1 is  $\geq$  about 16) then the assigned group= 0,
- if (RHI1 is  $>$  about 5.25 and if RHI1 is  $<$  about 7.0 ) then the assigned group=1,
- if (RHI1 is  $\geq$  about 7.0 and if RHI1 is  $<$  about 8.5 ) then the assign group=2, and
- if (RHI1 is  $\geq$  about 8.5 and if RHI1 is  $<$  about 16) then the assigned group=3.
163. (previously presented) The system of claim 162, comprising providing estimates using a predetermined mathematical formula defined as:
- $E0 = 0.55555 * BGMM1 + 2.95,$
- $E1 = 0.50567 * BGMM1 + 0.074 * L06 + 2.69,$

$E2 = 0.55555 * BGMM1 - 0.074 * L06 + 2.96,$

$E3 = 0.44000 * BGMM1 + 0.035 * L06 + 3.65;$  and

if (Group = 1) then  $EST2 = E1$ , or if (Group = 2) then  $EST2 = E2$ , or if (Group = 3) then  $EST2 = E3$ , otherwise  $EST2 = E0$ .

164. (previously presented) The system of claim 163, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06))  $EST2 = E0$ ,

if (RLO1 is  $\leq$  about 0.5 and RHI1 is  $\leq$  about 2.0) then  $EST2 = E0 - 0.25$ ,

if (RLO1 is  $\leq$  about 2.5 and RHI1 is  $>$  about 26 ) then  $EST2 = E0 - 1.5 * RLO1$ , and

if ((RLO1/RHI1) is  $\leq$  about 0.25 and L06 is  $>$  about 1.3) then  $EST2 = EST2 - 0.08$ .

165. (previously presented) The system of claim 164 for estimating the  $HbA_{1c}$  of a patient based on BG data collected over the first predetermined duration, said system comprising:

estimating  $HbA_{1c}$  using at least one of four predetermined mathematical formulas defined as:

a)  $HbA_{1c}$  = the  $EST2$  defined by claim 8 or as corrected by claim 10 or

b)  $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 + 1.873325$ , wherein

$BGMM1$  is the average BG (mmol/l) of claim 160,

$RLO1$  is the Low BG Index of claim 160,

RHI1 is the High BG Index of claim 160; or

- c)  $HbA1c = 0.682742 \cdot HBA0 + 0.054377 \cdot RHI1 + 1.553277$ ,  
wherein

HBA0 is a previous reference HbA1c reading taken  
about a second predetermined period prior to the  
estimate, wherein

RHI1 = is the High BG Index of claim 160; or

- d)  $HbA1c = 0.41046 \cdot BGMM + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 160.

166. (previously presented) The system of claim 165,  
wherein said second predetermined duration is about  
three months.
167. (previously presented) The system of claim 165,  
wherein said second predetermined duration ranges from  
about 2.5 months to about 3.5 months.
168. (previously presented) The system of claim 165,  
wherein said second predetermined duration ranges from  
about 2.5 months to six months.
169. (previously presented) The system of claim 165,  
wherein the validation of the sample using sample  
selection criteria of HbA1c estimate only if the first  
predetermined duration sample meets at least one of  
the following four criteria:
- a) a test frequency criterion wherein if the first  
predetermined duration sample contains an average  
of at least about 1.5 to about 2.5 tests per day;
- b) an alternative test frequency criterion only if  
the predetermined duration sample contains at

least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

- c) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio  $(RLO1/RHI1 \geq \text{about } 0.005)$ ,

wherein

RLO1 is the Low BG Index of claim 160,

RHI1 is the High BG Index of claim 160; or

- d) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio  $(N06 \geq \text{about } 3\%)$ ,

wherein

N06 is the percentage of readings during the night of claim 160.

170. (previously presented) The system of claim 169, wherein said third predetermined duration is at least 35 days.

171. (previously presented) The system of claim 169, wherein said third predetermined duration ranges from about 35 days to about 40 days.

172. (previously presented) The system of claim 169, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

173. (previously presented) The system of claim 165, wherein the validation of the sample using sample selection criteria of HbA1c estimate only if the first

predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
- b) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio  $(RLO1/RHI1 \geq \text{about } 0.005)$ ,  
wherein  
RLO1 is the Low BG Index of claim 160  
RHI1 is the High BG Index of claim 160; or
- c) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio  $(N06 \geq \text{about } 3\%)$ ,  
wherein  
N06 is the percentage of readings during the night of claim 160.

174. (previously presented) The system of claim 173, wherein said third predetermined duration is at least about 35 days.

175. (currently amended) A system for evaluating the HbA<sub>1c</sub> of a patient based on BG data collected over a first predetermined duration, said system comprising:  
a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;  
a database component operative to maintain a database identifying said BG data; and  
a processor programmed to:

prepare the data for estimating  $HbA_{1c}$  using a predetermined sequence of mathematical formulas defined as:

pre-process the data;

validate a sample of the BG data via sample selection criteria; and

estimate  $HbA_{1c}$  from said BG data if the sample is valid.

176. (previously presented) The system of claim 175, wherein said first predetermined duration is about 60 days.
177. (previously presented) The system of claim 175, wherein said first predetermined duration ranges from about 45 days to about 75 days.
178. (previously presented) The system of claim 175, wherein said first predetermined duration ranges from about 45 days to about 90 days.
179. (previously presented) The system of claim 175, wherein the preprocessing of the data for each patient comprise:
- conversion of plasma to whole blood BG mg/dl;
- conversion of BG measured in mg/dl to units of mmol/l;
- and
- computing Low Blood Glucose Index (RL01) and High Blood Glucose Index (RHI1).
180. (currently amended) The system of claim 175, wherein the preprocessing of the data for each patient using predetermined mathematical formulas is defined as:



conversion of plasma to whole blood BG mg/dl via  
 $BG = PLASBG \text{ (mg/dl)} / 1.12;$

conversion of BG measured in mg/dl to units of mmol/l)  
via  $BGMM = BG / 18;$  and

computing Low Blood Glucose Index (RLO1) and High  
Blood Glucose Index (RHI1) using a predetermined  
mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381,$  wherein BG is  
measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2,$  wherein

$RiskLO = Risk1$  if (BG is less than about 112.5) and  
therefore risk of LBGI exists, otherwise  
 $RiskLO = 0,$  and

$RiskHI = Risk1$  if (BG is greater than about 112.5)  
and therefore risk of HBGI exists, otherwise  
 $RiskHI = 0,$

$BGMM1 =$  average of BGMM per patient,

$RLO1 =$  average of RiskLO per patient,

$RHI1 =$  average of RiskHI per patient,

$L06 =$  average of RiskLO computed only for  
readings during the night, otherwise missing if  
there are no readings at night,

$N06, N12, N24$  are percentage of SMBG readings in  
time intervals ,

$NC1 =$  total number of SMBG readings in the first  
predetermined duration; and

$NDAYS =$  number of days with SMBG readings in the  
first predetermined duration.

181. (previously presented) The system of claim 180, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.
182. (previously presented) The system of claim 180, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:
- if (RHI1 is  $\leq$  about 5.25 or if RHI1 is  $\geq$  about 16) then the assigned group= 0,
- if (RHI1 is  $>$  about 5.25 and if RHI1 is  $<$  about 7.0 ) then the assigned group=1,
- if (RHI1 is  $\geq$  about 7.0 and if RHI1 is  $<$  about 8.5 ) then the assign group=2, and
- if (RHI1 is  $\geq$  about 8.5 and if RHI1 is  $<$  about 16) then the assigned group=3.
183. (previously presented) The system of claim 182, comprising providing estimates using a predetermined mathematical formula defined as:
- $E0 = 0.55555 \cdot BGMM1 + 2.95,$
- $E1 = 0.50567 \cdot BGMM1 + 0.074 \cdot L06 + 2.69,$
- $E2 = 0.55555 \cdot BGMM1 - 0.074 \cdot L06 + 2.96,$
- $E3 = 0.44000 \cdot BGMM1 + 0.035 \cdot L06 + 3.65;$  and
- if (Group = 1) then  $EST2 = E1$ , or if (Group = 2) then  $EST2 = E2$ , or if (Group = 3) then  $EST2 = E3$ , otherwise  $EST2 = E0$ .
184. (previously presented) The system of claim 183,

comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

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if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is ≤about 2.0) then
EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26 ) then
EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3)
then EST2=EST2-0.08.

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185. (previously presented) The system of claim 184 for estimating the HbA<sub>1c</sub> of a patient based on BG data collected over the first predetermined duration, said system comprising:

estimating HbA<sub>1c</sub> using at least one of four predetermined mathematical formulas defined as:

- a) HbA<sub>1c</sub> = the EST2 defined by claim 8 or as corrected by claim 10 or
- b) 
$$\text{HbA}_{1c} = 0.809098 \cdot \text{BGMM1} + 0.064540 \cdot \text{RLO1} - 0.151673 \cdot \text{RHI1} + 1.873325,$$
 wherein  
BGMM1 is the average BG (mmol/l) of claim 180,  
RLO1 is the Low BG Index of claim 180,  
RHI1 is the High BG Index of claim 180; or
- c) 
$$\text{HbA}_{1c} = 0.682742 \cdot \text{HBA0} + 0.054377 \cdot \text{RHI1} + 1.553277,$$
 wherein  
HBA0 is a previous reference HbA<sub>1c</sub> reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 180; or

$$d) \quad \text{HbA1c} = 0.41046 \cdot \text{BGMM} + 4.0775$$

wherein BGMM1 is the average BG (mmol/l) of claim 180.

186. (previously presented) The system of claim 185, wherein said second predetermined duration is about three months.
187. (previously presented) The system of claim 185, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.
188. (previously presented) The system of claim 185, wherein said second predetermined duration ranges from about 2.5 months to six months.
189. (previously presented) The system of claim 185, wherein the validation of the sample using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:
- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;
  - b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;
  - c) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio  $(\text{RLO1}/\text{RHI1}) \geq \text{about } 0.005$ ,
- wherein

RL01 is the Low BG Index of claim 180,

RHI1 is the High BG Index of claim 180; or

- d) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio (NO6  $\geq$  about 3%),

wherein

NO6 is the percentage of readings during the night of claim 180.

190. (previously presented) The system of claim 189, wherein said third predetermined duration is at least 35 days.

191. (previously presented) The system of claim 189, wherein said third predetermined duration ranges from about 35 days to about 40 days.

192. (previously presented) The system of claim 189, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

193. (previously presented) The system of claim 185, wherein the validation of the sample using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:

- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
- b) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio (RL01/RHI1  $\geq$  about 0.005),

wherein

RLO1 is the Low BG Index of claim 180

RHI1 is the High BG Index of claim 180; or

- c) a randomness of data criterion-2 wherein HbA<sub>1c</sub> estimate is validated or displayed only if the ratio (N06 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 180.

194. (previously presented) The system of claim 193, wherein said third predetermined duration is at least about 35 days.

195. (currently amended) A method for evaluating the HbA<sub>1c</sub> of a patient without the need for prior HbA<sub>1c</sub> information based on BG data collected over a first predetermined duration, said method comprising:  
preparing the data for estimating HbA<sub>1c</sub> using a predetermined sequence of mathematical formulas defined as:

pre-processing of the data[[:] ]  

validation of a sample of the BG data via sample selection criteria[[:] ]   and

estimating HbA<sub>1c</sub> from said BG data if the sample is valid; and

outputting the estimate to a user.

196. (previously presented) The method of claim 195, wherein said first predetermined duration is about 60 days.

197. (previously presented) The method of claim 195, wherein said first predetermined duration ranges from about 45 days to about 75 days.
198. (previously presented) The method of claim 195, wherein said first predetermined duration ranges from about 45 days to about 90 days.
199. (currently amended) The method of claim 195, wherein the preprocessing of the data for each patient comprise:
- conversion of plasma data to whole blood BG mg/dl;
  - conversion of BG measured in mg/dl to units of mmol/l;
  - and
  - computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).
200. (currently amended) The method of claim 195, wherein the preprocessing of the data for each patient using predetermined mathematical formulas is defined as:
- conversion of plasma to whole blood BG mg/dl via  $BG = PLASBG \text{ (mg/dl)} / 1.12$ ;
  - conversion of BG measured in mg/dl to units of mmol/l via  $BGMM = BG / 18$ ; and
  - computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:
    - $Scale = [\ln(BG)]^{1.0845} - 5.381$ , wherein BG is measured in units of mg/dl,
    - $Risk1 = 22.765(Scale)^2$ , wherein
    - $RiskLO = Risk1$  if (BG is less than about 112.5) and

therefore risk of LBGI exists, otherwise  
RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5)  
and therefore risk of HBGI exists, otherwise  
RiskHI=0,

BGMM1 = average of BGMM per patient,

RL01 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for  
readings during the night, otherwise missing if  
there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in  
time intervals ,

NC1 = total number of SMBG readings in the first  
predetermined duration; and

NDAYS = number of days with SMBG readings in the  
first predetermined duration.

201. (previously presented) The method of claim 200,  
wherein the N06, N12, N24 are percentage of SMBG  
readings in time intervals of about 0-6:59 hour time  
period; about 7-12:59 hour time period, and about 18-  
23:59 hour time period, respectively.
202. (previously presented) The method of claim 200,  
comprising assigning a group depending on the  
patient's computed High BG Index using a predetermined  
mathematical formula defined as:
- if (RHI1 is  $\leq$ about 5.25 or if RHI1 is  $\geq$ about 16)  
then the assigned group= 0,



if (RHI1 is > about 5.25 and if RHI1 is < about 7.0 ) then the assigned group=1,  
if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5 ) then the assign group=2, and  
if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

203. (previously presented) The method of claim 202, comprising providing estimates using a predetermined mathematical formula defined as:

$E0 = 0.55555 \cdot BGMM1 + 2.95,$   
 $E1 = 0.50567 \cdot BGMM1 + 0.074 \cdot L06 + 2.69,$   
 $E2 = 0.55555 \cdot BGMM1 - 0.074 \cdot L06 + 2.96,$   
 $E3 = 0.44000 \cdot BGMM1 + 0.035 \cdot L06 + 3.65;$  and  
if (Group = 1) then  $EST2 = E1$ , or if (Group = 2) then  $EST2 = E2$ , or if (Group = 3) then  $EST2 = E3$ , otherwise  $EST2 = E0$ .

204. (previously presented) The method of claim 203, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06))  $EST2 = E0$ ,  
if (RLO1 is ≤about 0.5 and RHI1 is ≤about 2.0) then  $EST2 = E0 - 0.25$ ,  
if (RLO1 is ≤about 2.5 and RHI1 is > about 26 ) then  $EST2 = E0 - 1.5 \cdot RLO1$ , and  
if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then  $EST2 = EST2 - 0.08$ .

205. (previously presented) The method of claim 204 for estimating the HbA<sub>1c</sub> of a patient based on BG data collected over the first predetermined duration, said method comprising:

estimating HbA<sub>1c</sub> using at least one of four predetermined mathematical formulas defined as:

- a)  $HbA_{1c} = \text{the EST2 defined by claim 8 or as corrected by claim 10}$  or
- b)  $HbA_{1c} = 0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 + 1.873325$ , wherein  
BGMM1 is the average BG (mmol/l) of claim 200,  
RLO1 is the Low BG Index of claim 200,  
RHI1 is the High BG Index of claim 200; or
- c)  $HbA_{1c} = 0.682742 * HBA0 + 0.054377 * RHI1 + 1.553277$ , wherein  
HBA0 is a previous reference HbA<sub>1c</sub> reading taken about a second predetermined period prior to the estimate, wherein  
RHI1 = is the High BG Index of claim 200; or
- d)  $HbA_{1c} = 0.41046 * BGMM + 4.0775$

wherein BGMM1 is the average BG (mmol/l) of claim 200.

206. (previously presented) The method of claim 205, wherein said second predetermined duration is about three months.

207. (previously presented) The method of claim 205, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

208. (previously presented) The method of claim 205,  
wherein said second predetermined duration ranges from  
about 2.5 months to six months.
209. (previously presented) The method of claim 205,  
wherein the validation of the sample using sample  
selection criteria of HbA1c estimate only if the first  
predetermined duration sample meets at least one of  
the following four criteria:
- a) a test frequency criterion wherein if the first  
predetermined duration sample contains an average  
of at least about 1.5 to about 2.5 tests per day;
  - b) an alternative test frequency criterion only if  
the predetermined duration sample contains at  
least a third predetermined sample period with  
readings with an average frequency of about 1.8  
readings/day;
  - c) a randomness of data criterion-1 wherein the  
HbA1c estimate is validated or displayed only if  
the ratio  $(RL01/RHI1 \geq \text{about } 0.005)$ ,  
wherein  
  
RL01 is the Low BG Index of claim 200  
  
RHI1 is the High BG Index of claim 200; or
  - d) a randomness of data criterion-2 wherein HbA1c  
estimate is validated or displayed only if the  
ratio  $(N06 \geq \text{about } 3\%)$ .  
  
wherein  
  
N06 is the percentage of readings during the  
night of claim 200.

210. (previously presented) The method of claim 209, wherein said third predetermined duration is at least 35 days.
211. (previously presented) The method of claim 209, wherein said third predetermined duration ranges from about 35 days to about 40 days.
212. (previously presented) The method of claim 209, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.
213. (previously presented) The method of claim 205, wherein the validation of the sample using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:
- a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and
  - b) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio  $(RLO1/RHI1 \geq \text{about } 0.005)$ , wherein  
RLO1 is the Low BG Index of claim 149  
RHI1 is the High BG Index of claim 200; or
  - c) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio  $(NO6 \geq \text{about } 3\%)$ , wherein

N06 is the percentage of readings during the night of claim 200.

214. (previously presented) The method of claim 213, wherein said third predetermined duration is at least about 35 days.

215. (currently amended) A system for evaluating the HbA<sub>1c</sub> of a patient without the need for prior HbA<sub>1c</sub> information based on BG data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

prepare the data for estimating HbA<sub>1c</sub> using a predetermined sequence of mathematical formulas defined as:

pre-process the data,

validate a sample of the BG data via sample selection criteria, and

estimate HbA<sub>1c</sub> from said BG data if the sample is valid; and

output the estimate to a user.

216. (previously presented) The system of claim 215, wherein said first predetermined duration is about 60 days.

217. (previously presented) The system of claim 215, wherein said first predetermined duration ranges from about 45 days to about 75 days.

218. (previously presented) The system of claim 215,

wherein said first predetermined duration ranges from about 45 days to about 90 days.

219. (currently amended) The system of claim 215, wherein the preprocessing of the data for each patient comprise:

conversion of plasma data to whole blood BG mg/dl;  
conversion of BG measured in mg/dl to units of mmol/l;  
and  
computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

220. (previously presented) The system of claim 215, wherein the preprocessing of the data for each patient using predetermined mathematical formulas defined as:

conversion of plasma to whole blood BG mg/dl via  
 $BG = PLASBG \text{ (mg/dl)} / 1.12$ ;  
conversion of BG measured in mg/dl to units of mmol/l)  
via  $BGMM = BG / 18$ ; and  
computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$ , wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$ , wherein

$RiskLO = Risk1$  if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise  
 $RiskLO = 0$ , and

$RiskHI = Risk1$  if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise

RiskHI=0,  
BGMM1 = average of BGMM per patient,  
RLO1 = average of RiskLO per patient,  
RHI1 = average of RiskHI per patient,  
L06 = average of RiskLO computed only for  
readings during the night, otherwise missing if  
there are no readings at night,  
N06, N12, N24 are percentage of SMBG readings in  
time intervals,  
NC1 = total number of SMBG readings in the first  
predetermined duration; and  
NDAYS = number of days with SMBG readings in the  
first predetermined duration.

221. (previously presented) A system for evaluating the  $HbA_{1c}$  of a patient without the need for prior  $HbA_{1c}$  information based on BG data collected over a first predetermined duration, said system comprising:
- a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;
  - a database component operative to maintain a database identifying said BG data; and
  - a processor programmed to:
    - prepare the data for estimating  $HbA_{1c}$  using a predetermined sequence of mathematical formulas defined as:
      - pre-process the data;
      - validate a sample of the BG data via sample

selection criteria; and  
estimate  $HbA_{1c}$  from said BG data if the  
sample is valid.

222. (previously presented) The system of claim 221,  
wherein said first predetermined duration is about 60  
days.

223. (previously presented) The system of claim 221,  
wherein said first predetermined duration ranges from  
about 45 days to about 75 days.

224. (previously presented) The system of claim 221,  
wherein said first predetermined duration ranges from  
about 45 days to about 90 days.

225. (currently amended) The system of claim 221, wherein  
the preprocessing of the data for each patient  
comprise:  
conversion of plasma data to whole blood BG mg/dl;  
conversion of BG measured in mg/dl to units of mmol/l;  
and  
computing Low Blood Glucose Index (RLO1) and High  
Blood Glucose Index (RHI1).

226. (currently amended) The system of claim 221, wherein  
the preprocessing of the data for each patient using  
predetermined mathematical formulas is defined as:  
conversion of plasma to whole blood BG mg/dl via  
 $BG = PLASBG \text{ (mg/dl)} / 1.12$ ;  
conversion of BG measured in mg/dl to units of mmol/l)  
via  $BGMM = BG / 18$ ; and  
computing Low Blood Glucose Index (RLO1) and High



Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$ , wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$ , wherein

$RiskLO = Risk1$  if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise

$RiskLO = 0$ , and

$RiskHI = Risk1$  if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise  $RiskHI = 0$ ,

BGMM1 = average of BGMM per patient,

RL01 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals ,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.